

REMARKS

Applicants have carefully reviewed the Final Office Action mailed July 10, 2008, prior to preparing this paper. Currently, claims 1, 5-16, 20, 24-41, 44 and 45 are pending in the application, wherein claims 1, 5-16, 20, 24-41, 44 and 45 have been rejected. Claims 20 and 36 have been amended with this paper. Claims 39-41 and 44 are hereby canceled without prejudice. The Specification has been amended to provide proper antecedent basis for the previously presented claim language. Claims 1, 5-16, 20, 24-38, and 45 remain pending. Favorable consideration of the above amendments and following remarks is respectfully requested.

Specification Objection

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter: the glass transition temperature being greater than the body temperature of the patient. Applicants direct the Examiner's attention to page 4-6 of the specification for discussion about the conditions and use of the claimed invention. Clearly, the specification indicates that the intended use of the device is within the body and it is desired that the shape of the guidewire be maintained during the procedure. In order to do that, the glass transition temperature should be above the internal body temperature of the patient to insure that the shape bestowed on the guidewire by the operator is retained when the guidewire is being navigated through the vasculature. As such, Applicants have amended one paragraph on page 5 of the specification to explicitly state this information and believe that the specification is now in condition to satisfy the objection. No new matter has been added.

Claim Rejections under 35 U.S.C. § 112

At page 2 of the Office Action, the Examiner rejected claims 1, 5-16, and 37 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully disagree with the Examiner and traverse the rejection. Applicants direct the Examiner's attention to page 4, line 6, through page 6, line 10 of the specification, which discusses the relationship between the polymer jacket 50 and the core wire 20.

It is well known in the art that super-elastic nickel titanium alloy cannot be shaped to a desired form under the forces normally encountered during use as part of a medical device (see Raman et al., U.S. Patent No. 5,368,049, at column 2, lines 57-64). The specification clearly describes the relationship claimed as such that even if a super-elastic nickel titanium alloy with

shape memory properties were subjected to the temperature at which those properties are activated, the forces of the shape memory properties would not be sufficient to overcome the stiffness or resistance to changing shape of the polymer jacket. Therefore, the super elastic nickel titanium alloy, as claimed, cannot be shaped independently of the polymer jacket, i.e., the polymer jacket is required to hold the shape of the super elastic nickel titanium alloy. Applicants submit that the specification is sufficiently enabling, and respectfully request that the Examiner withdraw the rejection.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 5, 6, 20, 24, 25, 36-41, 44 and 45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Raman et al. (U.S. Patent No. 5,368,049) in view of Schroepel (U.S. Patent No. 6,024,764). After careful review, Applicants respectfully traverse this rejection.

*** “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).” (MPEP 2143.03).

Independent claim 1 recites, in part, “an elongate core wire comprising a portion formed of a super elastic nickel titanium alloy...and a polymer jacket comprising a shape memory polymer attached to and surrounding the portion of the core wire formed of a super elastic nickel titanium alloy” (emphasis added). The Examiner asserts that Raman et al. disclose a formable cladding which surrounds the distal tapered portion of the guidewire. Applicants disagree with this assertion. Turning to the specification of Raman et al., Applicants direct the Examiner’s attention to column 4, lines 63-66, which states that the cladding terminates in a location that leaves “at least a section of superelastic alloy exposed” (emphasis added). The claimed invention surrounds the super elastic portion of the core wire, while Raman et al. teach away from this configuration.

The Examiner admits that Raman et al. do not disclose all the elements of claim 1. The Examiner asserts that Schroepel supplies the remaining elements. Applicants respectfully disagree, and submit that the cited references do not, alone or in combination, disclose all the claimed elements. Raman et al. do not disclose the super elastic portion of the core wire being surrounded by (and attached to) a polymer jacket. Schroepel does not remedy this shortcoming.

Therefore, Applicants believe that claim 1 is indeed patentable over the cited combination and request that the rejection be withdrawn.

Accordingly, for at least the reasons cited above and others, claims 5, 6 and 37, which depend from claim 1 and add additional elements thereto, are also believed to be patentable over the cited combination, and Applicants request that the rejections be withdrawn.

Independent claim 20 has been amended in this paper to recite, in part, “an elongate core wire comprising a distal tip portion formed of a super elastic nickel titanium alloy...and a polymer jacket attached to and surrounding the entire distal tip portion of the core wire”. Support for the amendment may be drawn from the drawings, such as Figures 2, 4 and 5, as well as from the Specification at page 4, lines 1-5. As discussed above with respect to claim 1, Raman et al. do not disclose this configuration and, in fact, teach away from it. Schroeppel does not remedy this missing element. Therefore, Applicants submit that claim 20 is patentable over the cited combination and respectfully request that the Examiner withdraw the rejection.

Accordingly, for at least the reasons cited above and others, claims 24, 25 and 38, which depend from claim 20 and add additional elements thereto, are also believed to be patentable over the cited combination, and Applicants request that the rejections be withdrawn.

Independent claim 36 has been amended in this paper to recite, in part, “a super elastic nickel titanium alloy core wire having a tapered portion and a distal end; and a polymer jacket...attached to and surrounding a portion of the core wire including the entire tapered portion and the distal end of the core wire”. Support for the amendment may be drawn from the drawings, such as Figures 2, 4 and 5, as well as from the Specification at page 4, lines 1-5. As discussed above, Raman et al. do not disclose this configuration and, in fact, teach away from it. Schroeppel does not remedy this missing element. Therefore, Applicants submit that claim 36 is patentable over the cited combination and respectfully request that the Examiner withdraw the rejection.

Independent claim 45 recites, in part, “an elongate core wire including a proximal portion and a distal portion, wherein at least the distal portion is formed of a super elastic metal...and a polymer jacket attached to and surrounding at least the distal portion of the elongate core wire formed of a super elastic metal” (emphasis added). As discussed above with respect to claim 1, Raman et al. state that the cladding terminates in a location that leaves “at least a section of superelastic alloy exposed” (emphasis added). The claimed invention surrounds the super elastic

portion of the core wire, while Raman et al. teach away from this configuration. Schroepfel does not appear to remedy this shortcoming. Therefore, Applicants submit that independent claim 45 is patentable over the cited combination, and respectfully request that the Examiner withdraw the rejection.

With regard to claims 39-41 and 44, they have been canceled, thereby rendering the rejection of these claims moot.

At page 4 of the Office Action, claims 7-16 and 26-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Raman et al. (U.S. Patent No. 5,368,049) in view of Schroepfel (U.S. Patent No. 6,024,764), and further in view of Takahashi (U.S. Patent No. 6,485,458). After careful review, Applicants respectfully traverse this rejection.

"If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." (MPEP 2143.03).

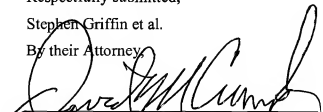
For at least the reasons discussed above, independent claims 1 and 20 are believed to be nonobvious over Raman et al. in view of Schroepfel. Takahashi does not remedy the shortcomings of this combination. Therefore, claims 7-16 and 26-35, which depend from and add additional elements to claims 1 and 20, respectively, are also believed to be nonobvious, and the Applicants request that the rejection be withdrawn.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Stephen Griffin et al.

By their Attorney,



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